

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)	
)	
Manfred BOHN et al.)	Group Art Unit: 1618
)	
Application No.: 10/606,229)	Examiner: L. Schlientz
)	
Filed: June 26, 2003)	Confirmation No.: 4228
)	
For: USE OF 1-HYDROXY-2-)	
PYRIDONES FOR THE)	
TREATMENT OF SEBORRHEIC)	
DERMATITIS)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 C.F.R. § 41.41

In support of the Appeal Brief filed on October 15, 2007 ("Appeal Brief"), and in reply to the Examiner's Answer ("Answer") dated December 13, 2007, Appellants present this Reply Brief. Appellants wish to clarify their position in light of the Examiner's statements in the Answer. Otherwise, Appellants rely on their arguments as set forth in the Appeal Brief.

I. Appendix C of Wortzman Declaration - Not All Cases of Seborrheic Dermatitis Respond to Dandruff Treatments

First, Appellants strongly disagree with the Examiner's response to Dr. Michael Wortzman's statement, as set forth in the declaration of record filed September 7, 2006. Answer at 9. Dr. Wortzman stated that "one of ordinary skill in the art would not find it

obvious to use a certain composition to treat SD, merely because the same composition is used to treat dandruff.” *Id.* Citing to Appendix C of Dr. Wortzman’s declaration, the Examiner contends that Appendix C, an excerpt from the Handbook of Nonprescription Drugs, suggests that dandruff, seborrheic dermatitis, and psoriasis “may be placed on a spectrum ranging from dandruff, a minor problem . . . to psoriasis, a clinical condition that can have significant physical, psychologic and economic consequences.” *Id.* The Examiner also quotes page 550 of the excerpt for its teaching that “many cases of seborrheic dermatitis will respond to the same non-prescription drug regimen used to treat dandruff.” *Id.* As Appellants will explain, even if these alleged teachings were true, they still do not detract from Dr. Wortzman’s statement set forth above.

Specifically, whether or not seborrheic dermatitis and dandruff can be placed on a spectrum of conditions does not alter the fact that these two conditions are entirely different, as the Examiner has acknowledged. See Answer at 9, ll. 1-6. Appellants respectfully remind the Examiner that when assessing obviousness, the entirety of a reference’s teaching must be considered and not only those portions that may weigh in the Examiner’s favor. See M.P.E.P. §2141.02, part VI. When one looks at the whole excerpt in Appendix C, a clear picture of the differences between seborrheic dermatitis and dandruff emerges. As an initial matter, Appendix C, at page 550 of the excerpt, teaches that “dandruff is not a true disease.” Further, most instructive on the overall differences is the table on page 551, which shows that dandruff affects the scalp specifically while seborrheic dermatitis affects the head and trunk. Dandruff manifests as thin, white or grayish flakes that are evenly distributed on the scalp in the absence of inflammation while seborrheic dermatitis manifests as patchy lesions with margins with

mild inflammation and oily, yellowish scales. Appendix C, Table at 551. The turnover rate of epidermal cells in seborrheic dermatitis is 3 fold faster than the turnover rate in dandruff. The incidence of dandruff peaks in early adulthood, levels off in middle age, and declines in the elderly, occurring rarely in individuals age 75 and older. See Appendix C at 550. In contrast, seborrheic dermatitis occurs mostly in middle-aged people and in the elderly. See Appendix C at 552.

Appellants also note that Dr. Wortzman's declaration was accompanied by two other references, Appendix A and Appendix B. The reference at Appendix A notes that there is a differential diagnosis between seborrheic dermatitis and dandruff. See Appendix A at 9 of 17. The reference at Appendix B also distinguishes between seborrheic dermatitis and dandruff. See Appendix B at 164, section I. Given these numerous differences between seborrheic dermatitis and dandruff as demonstrated by Appendices A-C, one of ordinary skill in the art would not have found it obvious to use a composition on seborrheic dermatitis just because the composition can be used on dandruff.

Moreover, not all treatments for dandruff can be used on seborrheic dermatitis nor can all treatments for seborrheic dermatitis be used on dandruff. The group of treatments for each condition is not completely overlapping. For example, topical corticosteroids are indicated for treating seborrheic dermatitis when erythema persists. But these corticosteroids are not indicated for the treatment of dandruff. See Appendix C at 552. There is nothing in the references cited by the Examiner to suggest that the 1-hydroxy-2-pyridone recited in the claims would be a treatment that could be used on seborrheic dermatitis as well as dandruff.

In sum, the preponderance of the teaching in Appendix C shows that seborrheic dermatitis and dandruff are two distinct conditions. As Dr. Wortzman, an expert in the field of dermatology, has explained, one of ordinary skill in the art would not have found it obvious to use a composition to treat seborrheic dermatitis simply because the composition might be used to treat dandruff. Wortzman Declaration, para. 7. Appellants maintain that the rejection should be withdrawn for this reason alone.

II. Declaration of Mr. Kevin Kriel - Appellants Provided a Showing of Commercial Success

Second, Appellants provided the declaration of Mr. Kriel as evidence of the commercial success of Loprox® Shampoo. The Examiner continues to dismiss this declaration as proof of non-obviousness because, the Examiner contends, the discussion of Loprox® Shampoo in the declaration is not “commensurate in scope with the claims.” Answer at 10. Appellants disagree. As noted in the Appeal Brief, Mr. Kriel’s declaration discusses the commercial success of Loprox® Shampoo, which falls within the scope of the features of the claims on appeal. Appeal Brief at 18. The Examiner suggests that the claims on appeal potentially read on “thousands of potential antifungal compounds.” Answer at 11. Whether this statement is true or not (and Appellants do not concede that it is), clearly it would be unreasonable to expect Appellants to address each one of those potential compounds in a declaration. Indeed, the Federal Circuit has explained that

[f]or objective evidence [of commercial success] to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *Stratoflex*, 713 F.2d at 1539, 218 U.S.P.Q. (BNA) at 879. “A prima facie case of nexus is generally made out when the patentee shows both that there is commercial

success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392, 7 U.S.P.Q.2D (BNA) 1222, 1226 (Fed. Cir.), *cert. denied*, 488 U.S. 956, 102 L. Ed. 2d 383, 109 S. Ct. 395 (1988). To the extent that the patentee demonstrates the required nexus, his objective evidence of nonobviousness will be accorded more or less weight. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306, 227 U.S.P.Q. (BNA) 657, 674 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017, 89 L. Ed. 2d 315, 106 S. Ct. 1201 (1986).

In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995). Here, Mr. Kriel's declaration addresses the formulation, Loprox® Shampoo, that has been developed for commercialization. See Appeal Brief at 17 and Kriel Declaration generally. The commercial success of Loprox® Shampoo is based on the elements present in the claims on appeal. Kriel Declaration, para. 1. Appellants have established a nexus between the evidence and the merits of the claimed invention, as discussed at length in the Appeal Brief, therefore making Mr. Kriel's declaration dispositive of the invention's non-obviousness. Appeal Brief at 17 and 18.

The Examiner also continues to caution that commercial success may be based on other elements that are not present in the claims such as heavy promotion, a shift in advertising, or "other business events." *Id.* Here, however, the relevant products are prescription products. Physicians prescribe such products based primarily on efficacy, rather than advertising or price. Kriel Declaration, para. 6. Appellants maintain, therefore, that the rejection should be withdrawn for this additional reason.

III. The Standard for Identifying Analogous Art Is Not the Standard for Obviousness

Third, the Examiner continues to suggest that one of ordinary skill in the art “would have been motivated to combine the references [cited] and make the modification because they are drawn to the same technical field . . . share common utilities, and are pertinent to the problem with which applicant is concerned. MPEP 2141.01(a).” Answer at 6. The MPEP section referred to by the Examiner speaks to the factors considered when determining whether a reference is analogous art for the purposes of obviousness. This is not the standard for determining obviousness itself. The Examiner’s alleged motivation to combine does not invoke any of the specific characteristics of the invention on appeal. See Appeal Brief at 14. Such reasoning could be used generically on any invention and does not provide support for a charge of obviousness against the specific invention on appeal. Appellants maintain that the rejection should be withdrawn for this additional reason.

IV. Appellants Have Not Conceded That Seborrheic Eczema Is Equivalent to Seborrheic Dermatitis

Finally, the Examiner summarized a portion of Appellants’ argument as follows:

Appellants argue that the examiner acknowledges that Dittmar does not teach a method of treating SD, and relies on Hanel, which discusses the treatment of seborrheic eczema (i.e. which is defined as equivalent to seborrheic dermatitis via an on-line medical dictionary) to remedy the shortcomings of Dittmar.

Answer at 7. Appellants disagree with this summary. Appellants never conceded that seborrheic eczema was defined as an equivalent to seborrheic dermatitis. Rather, in the Appeal Brief, Appellants argued that

[d]uring prosecution, the Examiner repeatedly acknowledged that *Dittmar* does not teach a method for treating SD, and relies on *Hanel*, which discusses the treatment of seborrheic eczema, to remedy the shortcomings of *Dittmar*. The Examiner then attempted to link seborrheic eczema to seborrheic dermatitis by referencing an on-line medical dictionary. Appellants maintain that even if one of ordinary skill in the art did consider seborrheic eczema to be the same condition as SD, there is still no nexus between *Dittmar's* treatment of dandruff and *Hanel's* treatment of seborrheic eczema.

Appeal Brief at 10. This argument is not tantamount to agreeing that that seborrheic eczema was defined as an equivalent to seborrheic dermatitis. Thus, Appellants argued in the alternative, noting that *even if* one of ordinary skill in the art did consider seborrheic eczema to be the same condition as seborrheic dermatitis, there is still no nexus between *Dittmar's* treatment of dandruff and *Hanel's* treatment of seborrheic eczema. Accordingly, Appellants maintain that the rejection should be withdrawn for this additional reason.

V. Conclusion

For the reasons set forth above and in the Appeal Brief, claims 14-23 and 26-29 remain allowable and Appellants request reversal of the Examiner's rejection against these claims.


If there are any fees due in connection with filing this brief, which are not enclosed herewith, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 12, 2008

By: _____

A handwritten signature in black ink, appearing to read "Thalia V. Warnement", is written over a horizontal line. The signature is fluid and cursive, with a large, sweeping flourish at the end.

Thalia V. Warnement
Reg. No. 39,064